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510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	CareFusion 303, Inc.
Address	10020 Pacific Mesa Blvd., San Diego, CA 92121
Phone number	(858) 617-5889
Fax number	(858) 617-5960
Establishment Registration Number	2016493
Name of contact person	Gabriela Muranevici
Date prepared	February 22, 2011
Name of device	
Trade or proprietary name	Alaris® PC unit Module 8000 with software correction
Common or usual name	Infusion Pump
Classification name	Pump, Infusion
Classification panel	Class II
Regulation	21 CFR 880.5725
Product Code(s)	FRN
Legally marketed device(s) to which equivalence is claimed	Modification to the Alaris PC unit Module 8000
Reason for 510(k) submission	CareFusion 303, Inc. is submitting this **Traditional 510(k)** to inform the FDA of a correction to the Alaris PC unit Model 8000 software.
Device description	The Alaris System is a modular system that consists of a point-of-care unit (PC unit) that provides the main user interface and power supply for the associated infusion and monitoring modules. This update is only for the Alaris PC unit Module 8000 software correction and does not require any change to the associated modules, systems, or accessories of the Alaris System. The basic functionality and existing features as described in the original and subsequent 510(k) submissions for the Alaris System and associated modules will not change.

Intended use of the device	See Indications for Use statement
Indications for use	The Alaris® PC Unit is the main user interface unit and power supply of the Alaris® System, a modular system to be used with Alaris® System modules (aka Medley™ System modules) intended for use in today's growing professional healthcare environment for facilities that utilize infusion and/or monitoring devices. The specific intended use for each Alaris® System module is specified in its respective submission.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	New Device	Predicate [Device Name] [510(k) number]
With the exception of the software correction presented in this submission, the Alaris PC unit is essentially the same as the originally submitted predicate device. The intended use, principles of operation, fundamental scientific technology, method of manufacture, and application are essentially the same.	Alaris PC unit Module 8000 with software correction	Modification to the Alaris PC unit Module 8000 K091308

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Gabriela Muranevici
Principal Regulatory Affairs Specialist
Carefusion, Incorporated
10020 Pacific Mesa Boulevard
San Diego, California 92121

MAR 2 6 2012

Re: K110535
Trade/Device Name: Alaris PC Unit Module 8000
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: March 21, 2012
Received: March 22, 2012

Dear Ms. Muranevici:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110535

Device Name: Alaris® PC Unit

Indications for Use:

The Alaris® PC Unit is the main user interface unit and power supply of the Alaris® System, a modular system to be used with Alaris® System modules (aka Medley™ System modules) intended for use in today's growing professional healthcare environment for facilities that utilize infusion and/or monitoring devices. The specific intended use for each Alaris® System module is specified in its respective submission.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ion Sign-Off)
ion of Anesthesiology, General Hospital
tion Control, Dental Devices

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